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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,953	06/17/2002	Anthony Douglas Shannon	28594/38247	2556

4743 7590 12/16/2004

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,953	SHANNON ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-50* is/are pending in the application.

4a) Of the above claim(s) *32-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/8/02,6/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 7/6/04 is acknowledged. The traversal is on the ground(s) that it is no burden to search the additional groups. This is not found persuasive because in this 371 application the standard is Lack of Unity and special technical feature. Applicant has not argued the reason or art cited in the Lack of Unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 32-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 21-31 are under consideration in the action.

Information Disclosure Statement

Signed and initialed copies of the IDS papers filed April 8, 2002 and June 19, 2002 are enclosed.

Priority

The Office notes in the Preliminary Amendment the insertion of the priority claim before the first line of the specification which includes a claim to the PCT and foreign application on which it is based.

Claim Objections

Claims 25-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires production of an antigenic peptide. Claims 25-28 require virus and this is not an antigenic peptide. The claims will be treated as if they only recite fragment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of what defines "derived" is not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a subunit vaccine of BVDV, does not reasonably

provide enablement for any subunit vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The invention is drawn to a method of making a immunogenic complex comprising a HSP and an antigenic peptide.

The prior art recognizes that HSPs complexed with peptide antigens without adjuvant give rise to immunologically significant responses (Schirmbeck et al. (Euro J of Immunol, from IDS, page 1740, first paragraph).

The working examples are drawn to BVDV.

There is no guidance on how to practice the invention with whole virus or bacterium. There is no guidance on how to practice the invention all pathogens. It is well known in the art that Hepatitis A virus does not produce a protective immune response as a subunit, but only as a whole virus. There are no known protective vaccines against HIV.

It would require undue experimentation to use the invention to the scope as claimed now.

Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava (WO 99/29834, from IDS).

The claims are drawn to a method of producing an immunogenic complex comprising a step wherein the cell has been subjected to a stimulus that causes induction of heat shock response.

Srivastava teaches a method of making an immunogenic complex comprising HSP and heterologous antigenic peptide in insect cells (page 32 and claim 6).

The specification does not show this step of stimulus to induce HSPs makes a difference in the product made (in structure or quantity) and applicant has not shown

that the product made is immunologically different from a protein produced without heat shock.

HSP are part of the normal function of the cell (Rico et al., IDS, page 347, column 1) and it would be expected that they would be present in cells normally. So it would be expected that any protein fragment produced in baculovirus would have hsp associated with it.

Applicant has not shown that the product has a different size or requires special purification to have the asserted properties.

Applicant has not shown that the recited product is immunologically different from a non-heat shocked produced antigen. The vaccine antigens made (Table 9) and the antigens tested (Table 11) do not have a control for different preparations of the same antigen.

Thus, it is concluded that the step does not confer any difference in the product.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava and Deregt *et al.* (1998 Virus Res Vol 57, pages 171-181).

The claims are drawn to a method of producing an immunogenic complex comprising a step wherein the cell has been subjected to a stimulus that causes induction of heat shock response.

Srivastava is discussed above and teaches making immunogenic complexes with HSPs.

Srivastava does not teach virus or BVDV as the heterologous antigenic peptide.

Deregt *et al.* teach that BVDV is a known pathogen of bovines and that the E2 region has been used as a subunit vaccine (page 172, column 1, second full paragraph).

One of ordinary skill in the art would have been motivated to use the general vaccine method of Srivastava to make other immunogenic formulations because Srivastava teaches that the made compositions give rise to immune responses. One of ordinary skill in the art would have been motivated to use BVDV because it is known that it is a common virus and has economic implications because of the disease it causes. One of skill in the art would have the expectation of success because the E2 of Deregt *et al.* is taught to give rise to neutralizing antibodies which lead to a protective response. One of ordinary skill in the art knowing the antibodies of Deregt *et al.* would

be able to make fragments of E2 that have the neutralizing epitopes for use in the method of Srivastava.

Thus, it would be prima facie obvious to use the method of Srivastava with the antigen of Deregt *et al.* to make an immunogenic composition.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill

JAMES HOUSEL 12/13/04
SUPERVISORY PATENT EXAMINER
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